REMARKS/ARGUMENTS

Amendments to the Claims

Claims 1, 15, and 16 are amended. Claims 4-8 and 22 are either original or previously presented claims. Claims 9-14 and 17-21 are canceled (with claims 2-3 having been previously canceled). New claims 23 and 24 are presented. With the amendments, claims 1, 4-8, 15-16, and 22-24 remain in the application.

Claim 1 is amended to specify that the epothilone is provided at a dosage level between about 1 mg/m^2 and about 200 mg/m^2. Support is found at paragraph [0013].

Claim 1 also is amended to specify that the pharmaceutically acceptable carrier comprises 10 to 62.5 % v/v water, 12.5 to 65 % v/v ethanol, and 10 to 25 % v/v polyoxyethylene sorbitan monooleate. Support is found at paragraphs [0020] to [0022] and Table 1, page 13.

Claim 15 is amended to specify that the reconstitution solvent comprises 25 to 65 % v/v water, 10 to 60 % v/v ethanol, and 15 to 25 % v/v polyoxyethylene sorbitan monooleate. Support is found at paragraph [0022]. Dependent claim 16, specifying a preferred range for the polyoxyethylene sorbitan monooleate, finds support at paragraph [0021].

New claims 23 and 24 specify that preferred dosage levels of between about 10 mg/m^2 and about 150 mg/m^2 and about 15 mg/m^2 and about 50 mg/m^2, respectively. Support is found at paragraph [0036].

Rejection under 35 USC §112

Claim 1 and its dependent claims were rejected in the FOA, the Examiner holding that the phrase "wherein the epothilone is provided in a therapeutically acceptable concentration upon administration to a patient" rendered the claim indefinite. The rejection is traversed.

It is submitted that Claim 1 as amended, and, consequently, its dependent claims, are not indefinite. The "therapeutically acceptable concentration" language has been replaced by "between about 1 mg/m^2 and about 200 mg/m^2". The new language specifies a numeric range that is objectively determinable. Therefore, claim 1 as amended is not indefinite.

In view of the amendment and the foregoing remarks, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 USC §102(b) (Hofmann et al., US 6,194,181 B1)

The Examiner rejected claim 1 and its dependent claims as anticipated under §102(b) by Hofmann et al., US 6,194,181 B1 ("Hoffman"). The Examiner argued that Hoffman discloses a pharmaceutical composition comprising an epothilone (epothilone B), β-cyclodextrin, and a pharmaceutically acceptable carrier (water) and pointed to Example 2A, Table 1, col. 24, line 32 to col. 25, line 17. The rejection is traversed.

Firstly, it is submitted that the Examiner's characterization of the composition of Hoffman's Example 2A as a "pharmaceutical composition" is inapt. Example 2A pertains to a procedure for producing epothilones A and B by fermentation of a microorganism. While a pharmaceutically acceptable carrier can be water, the converse is not true: not every kind of water is a pharmaceutically acceptable carrier. Only water meeting purity and sterility requirements is a pharmaceutically acceptable carrier. Such water is often referred to as "water for injection" or "WFI". See, e.g., the instant application at page 13, paragraphs [0003] and [0004] and Table 1; van Hoogevest, US 6,683,100 B2 ("van Hoogevest", of record), at col. 12, line 2; and Mutz et al., US 6,380,227 B1 (also of record), at col. 18, line 23. The water of Hoffman's Example 2A most definitely is not a pharmaceutically acceptable carrier: no prudent physician would administer to a patient a preparation made with water taken from a microbial fermentation vat. Thus, it is respectfully submitted that the composition disclosed by Hoffman is not a pharmaceutical composition.

Secondly, even if one assumed, for the sake of argument, that Hoffman's composition is a "pharmaceutical composition", Applicants respectfully submit that Hoffman does not anticipate claim 1 as amended. Amended claim 1 specifies that the pharmaceutically acceptable carrier comprises polyoxyethylene sorbitan monooleate as one of its components.[1] Hoffman does not disclose or suggest such a component.

In view of the foregoing arguments, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 USC §102(e) (van Hoogevest)

Independent claims 1, 9, and 15 and certain of their dependent claims were rejected in the FOA under §102(e) as anticipated by van Hoogevest.

In respect of claim 1, the Examiner pointed to van Hoogevest's Examples 11 to 14 (col. 12, lines 26-39) as disclosing "a pharmaceutical composition comprising an epothilone (epothilone B) and hydroxypropyl-β-cyclodextrin together with a pharmaceutically acceptable carrier (water)." The rejection as applied to claim 1 is traversed.

Claim 1 as amended specifies that the pharmaceutically acceptable carrier comprises polyoxyethylene sorbitan monooleate as one of its components. van Hoogevest lists many materials as possible ingredients for his pharmaceutical compositions: see, e.g., col. 2, lines 30-64, and col. 3, lines 14-26. However, polyoxyethylene sorbitan monooleate is neither disclosed nor suggested by van Hoogevest. Therefore, it is submitted that claim 1 as amended is not anticipated by or obvious over van Hoogevest.

The rejection of independent claim 9 over van Hoogevest is mooted in view of its cancellation.[2]

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[1] For the Examiner's reference, item D03 in the companion Information Disclosure Statement contains a structural formula for polyoxyethylene sorbitan monooleate.

[2] The FOA incorrectly labeled claim 9 as a dependent claim.

The rejection as applied to independent claim 15 is traversed for the same reasons as presented above in respect of claim 1.

In view of the foregoing, reconsideration and withdrawal of the rejections 1 and 15 and their dependent claims over van Hoogevest is respectfully requested.

Rejection under 35 USC §103(a) (Hoffman)

This rejection is unclear. While the Examiner initially wrote that "[c]laims 9-14 are rejected under 35 USC 103(a) as being unpatentable over Hoffman" (emphasis added), he followed with an extended discussion applying Hoffman against claim 1. In any event, if the rejection was intended to apply to claim 1, it is traversed; conversely, if the rejection was intended to apply to claims 9-14, it is mooted in view of their cancellation.

To the extent that the Examiner intended to reject claim 1 as obvious over Hoffman, it is respectfully submitted that claim 1 as amended is not obvious over Hoffman. Hoffman does not disclose a "pharmaceutical composition" and does not disclose or suggest the use of polyoxyethylene sorbitan monooleate, both points having been elaborated upon hereinabove. Therefore, reconsideration and withdrawal of the §103(a) rejection over Hoffman is respectfully requested.

Rejection under 35 USC §103(a) (van Hoogevest)

Claims 15-21 stand rejected under §103(a) as obvious over van Hoogevest. The rejection is traversed.

As noted above, van Hoogevest does not disclose or suggest the use of polyoxyethylene sorbitan monooleate. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

Extension of time

The Commissioner is authorized to charge against Deposit Account No. 50-2544 the fee for the submission of this RCE and for two months' extension of time and any other fees that might be necessary under 37 C.F.R. §§1.16, 1.17, or 1.18, and to credit any overpayments to the same account. A RCE Transmittal form (PTO/SB/30) confirming such authorization is submitted in duplicate.

Conclusion

In conclusion, it is submitted that this application is in condition for allowance. A prompt and favorable action is earnestly solicited.

Respectfully submitted,

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Date

Yuan Chao
Reg. No. 32,118
Telephone (510) 731-5156
Facsimile (510) 731-5143